

**UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MISSOURI**

ALANA SWINDELL, INDIVIDUALLY
AND AS MOTHER AND GENERAL
GUARDIAN OF L.S., A MINOR,

Plaintiff,

v.

WAL-MART STORES, INC.

Defendant.

Case No. 3:22-cv-5085

JURY TRIAL DEMANDED

Complaint

Plaintiff Alana Swindell (“Plaintiff Mother”) and Plaintiff L.S. (“Plaintiff Child”), pursuant to Rule 17(c)(1)(A), by and through their undersigned counsel, bring this Complaint for damages against Defendant, Wal-Mart Stores, Inc., and in support state the following:

1. This is an action brought on behalf of Plaintiffs Alana Swindell, the natural and general guardian and mother of L.S., a minor, and L.S. arising out of the failure of Defendant to warn about the dangers of prenatal exposure to Paracetamol, also known as Acetaminophen. As a result, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

2. Defendant entirely failed its duty to adequately warn of the hazards of prenatal exposure to Acetaminophen, which was a direct and proximate cause of Plaintiffs injuries and associated damages.

Statement of parties

3. At all material times Plaintiffs have been citizens and residents of Jasper County, Missouri and the United States.

4. Wal-Mart is incorporated in Delaware, with its principal place of business in Arkansas.

5. Wal-Mart is a multinational company involved in the research, development, testing, manufacture, labeling, production, marketing, promotion, and sale of Acetaminophen through its store brand “Equate.”

6. Wal-Mart is liable to Plaintiffs for damages they suffered, arising from Defendant’s design, manufacture, marketing, labeling, distribution, sale, and placement of the defective Acetaminophen into the market, effectuated directly and indirectly through its directors, officers, agents, servants, and employees, all acting within the course and scope of their authority, agency, and employment.

7. Wal-Mart is vicariously liable for the acts and omissions of its employees and agents, who were at all material times acting on behalf of Wal-Mart and within the scope of their employment or agency.

Venue and jurisdiction

8. This Court has subject-matter jurisdiction under 28 U.S.C. § 1332(a), based on complete diversity of citizenship between Plaintiffs and Defendants.

9. The amount in controversy exceeds \$75,000.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because events or omissions giving rise to Plaintiffs’ claims occurred in this judicial district.

11. Defendant has and continues to conduct substantial business in the State of Missouri and in this District, distributes Acetaminophen in this District, receives substantial compensation and profits from sales of APAP in this District, and has made material omissions and misrepresentations and breaches of warranties in this District, so as so subject Defendant to in personam jurisdiction in this District.

12. Defendant is registered to transact business in Missouri.

Facts common to all counts

**Acetaminophen is marketed as the safe pain reliever for pregnant women, but
Acetaminophen causes serious disorders in children born to women who take
Acetaminophen during pregnancy**

13. Acetaminophen has long been marketed as the safest, and the *only* appropriate, over-the-counter pain relief drug on the market for pregnant women.

14. Based upon information and belief, a majority of women who use Acetaminophen during pregnancy do so electively for the treatment of headaches, muscle pain, and back pain.

15. These pregnant women electively choose to take Acetaminophen because Defendant has marketed Acetaminophen as a safe pain reliever for pregnant women.

16. But increasing experimental and epidemiological research has shown that prenatal exposure to Acetaminophen alters fetal development, which significantly increases the risks of neurodevelopmental disorders, including but not limited to, autism spectrum disorder (ASD) and attention-deficit/hyperactivity disorder (ADHD).

17. Undisturbed development of the human brain in utero is vital to the health and wellness of a child's development. The human brain is vulnerable and extremely sensitive in utero.

During this sensitive time-period in utero, certain chemicals have been found to cause permanent brain injury at low exposure levels.

18. Once ingested by the mother, Acetaminophen is known to readily cross the placenta and blood-brain barrier.

19. ASD is a serious neurological and developmental disorder that affects how people interact with others, communicate, learn, and behave.

20. There are three functional levels of ASD, with Level 1 requiring support with activities of daily living, Level 2 requiring substantial support with activities of daily living, and Level 3 requiring very substantial support with activities of daily living.

21. Treatments for ASD include behavioral management therapy, cognitive behavior therapy, joint attention therapies, medications, occupational therapy, physical therapy, social skill training, and speech-language therapy. Treatment for ASD lasts a lifetime as there is no cure.

22. ADHD is a chronic neurodevelopmental disorder resulting in attention difficulty, hyperactivity, and impulsiveness.

23. ADHD begins in childhood and persists through adulthood. ADHD contributes to low self-esteem, troubled relationships, and difficulty with school, work, and familial relationships.

24. Treatments of ADHD, include, but are not limited to, chronic medication usage and various therapies. Treatment for ADHD lasts a lifetime as there is no cure.

25. The Center for Disease Control and Prevention (CDC) found that 1 in 44 (2.3%) of eight-year-old children have been diagnosed with ASD.

26. This represents an increase from a prior CDC finding that 1 in 68 U.S. children born in 2002 have ASD, which already represented a more than a 100% increase compared with children born a decade prior.

27. As of 2019, 8.8% of children had been diagnosed with ADHD.

28. Parental awareness and changes in diagnoses do not account for the rapid rise in these diagnoses.

29. Rather, prenatal Acetaminophen exposure explains a trending increase in diagnosis.

30. For years, the scientific community has published studies showing that prenatal ingestion of Acetaminophen can cause ASD and ADHD.

31. For instance, since 2013, there have been six European birth cohort studies, examining over 70,000 mother-child pairs, showing the association between prenatal use of Acetaminophen and ASD and ADHD.

32. The overall body of scientific evidence shows that prenatal use of Acetaminophen can cause ASD and ADHD in the child and that substantial prolonged prenatal exposure to Acetaminophen, particularly during the third trimester of pregnancy, is a substantial factor in causing ASD and ADHD.

33. During all relevant times, Defendant was engaged in the business of manufacturing and selling Acetaminophen products in the United States, and the weight of the scientific evidence shows prenatal exposure to Acetaminophen significantly increases the risk of neurodevelopmental disorders in children exposed to Acetaminophen prenatally, including but not limited to, ASD and ADHD.

34. The scientific evidence regarding the risks of in utero exposure of Acetaminophen was available to Defendant, and Defendant knew or should have known that prenatal use of Acetaminophen can cause ASD or ADHD.

35. Based on information and belief, Defendant has concealed from consumers, like Plaintiff Mother, the link between prenatal Acetaminophen exposure neurodevelopmental harm.

36. Moreover, despite knowing that prenatal use of Acetaminophen can cause ASD or ADHD, Defendant continues to market Acetaminophen as the safe pain reliever for pregnant women, making mothers believe they are choosing a safe drug for even minor aches, pains, and headaches.

Plaintiff Mother took Acetaminophen while pregnant, and it caused ASD and ADHD in Plaintiff Child

37. Plaintiff Mother began using Defendant's over-the-counter Acetaminophen product, Equate, in or around July 2016 when she was pregnant with her son, Plaintiff L.S.

38. During the course of her pregnancy, Plaintiff Mother frequently took Acetaminophen multiple times per week to relieve her headaches.

39. Plaintiff Mother believed it was safe for her to take Acetaminophen during her pregnancy.

40. There is no warning on Defendant's Acetaminophen label, the Equate label, specifically addressing the risks of ASD and ADHD if a mother ingests Acetaminophen while pregnant.

41. Had Plaintiff Mother known of the risk of taking Acetaminophen while pregnant, specifically that it could cause ASD and ADHD in her child, she would not have taken Acetaminophen.

42. Plaintiff Child was born on April 10, 2017.
43. Plaintiff Mother started to have concerns about Plaintiff Child's development.
44. Plaintiff Child was ultimately diagnosed with ASD when he was five years old.
45. Plaintiff Child was also diagnosed with ADHD when he was five years old by his primary care doctor.
46. Plaintiff's Child ASD and ADHD put an incredible strain on Plaintiff Mother and their family.
47. Social interaction is incredibly challenging for Plaintiff Child.
48. Because of Plaintiff's Child's inability to pay attention and get along with peers, Plaintiff Child is home schooled.
49. Plaintiff Child has harmed himself and others on multiple occasions.
50. Plaintiff Child has difficulty going into public and making friends.
51. Plaintiff Child has difficulty with speech, taking directions, and finishing tasks.
52. Plaintiff Child is easily angered and has no thought to what consequences may follow.
53. Plaintiff Mother worries about Plaintiff Child's future and his ability to thrive in the world given the limitations of his ASD and ADHD.

Estoppel and tolling of statute of limitations

54. Due to Defendant's acts of fraudulent concealment, Defendant is estopped from relying on any statutes of limitations or repose. Such acts include Defendant's intentional concealment from Plaintiff Mother and the general public that Acetaminophen is defective when there is prenatal exposure, while continuing to market the product with the adverse effects described in this Complaint.

55. Given Defendant's affirmative actions of concealment by failing to disclose information about the defects known to them but not the public—information over which Defendant had exclusive control—and because Plaintiff could not reasonably have known that Acetaminophen was defective, Defendant is estopped from relying on any statutes of limitations that might otherwise be applicable to the claims asserted in this Complaint.

56. Plaintiffs have, in any event, brought this action less than five years from the time that they discovered, or in the exercise of due diligence should have discovered, the harm and its cause.

Count I: Strict liability – failure to warn

57. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

58. At the time of Plaintiffs' injuries, Defendant's drug, Acetaminophen, was defective and unreasonably dangerous when ingested by pregnant women, who are reasonably foreseeable consumers of the drug.

59. At all relevant times, Defendant engaged in the business of testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, and promoting Acetaminophen products that are defective and unreasonably dangerous to consumers, including Plaintiff Mother, because they did not contain adequate warnings or instructions concerning the dangerous characteristics of ingesting Acetaminophen during pregnancy. These actions were under the control and supervision of Defendant. At all relevant times, Defendant researched, manufactured, distributed, marketed, labeled, promoted, and sold Acetaminophen and aimed the marketing at the ultimate consumer. Defendant was at all relevant times controlled and directed the retail and promotion of Acetaminophen products marketed and sold in this District.

60. Defendant had a duty to warn of the risks associated with the use of Acetaminophen products.

61. The Acetaminophen ingested by Plaintiff Mother during pregnancy was in the same or substantially similar condition as it was when it left possession of the Defendant.

62. Defendant expected and intended the Acetaminophen product to reach users such as Plaintiff Mother in the condition in which the product was sold.

63. Plaintiff Mother did not materially alter the Acetaminophen drug product before ingestion.

64. Plaintiff Mother ingested the Acetaminophen drug product as indicated on the drug's label.

65. Plaintiff Mother was unaware of the defects and dangers of the Acetaminophen products, and was unaware that prenatal exposure increases the risk of brain and behavioral development of her child.

66. Defendant's label to consumers lacks any warning specific to pregnant women. The information that Defendant did provide or communicate failed to contain relevant warnings, hazards, and precautions that would have enabled consumers such as Plaintiff Mother to utilize the products safely and with adequate protection, or decide to not ingest the product at all.

67. This alleged failure to warn is not limited to the information contained on Acetaminophen's labeling. The Defendant was able, in accord with federal law, to comply with relevant state law by disclosing the known risks associated with Acetaminophen through other non-labeling mediums, such as promotion, advertisements, public service announcements, and public information sources. But the Defendant did not disclose these known risks through any medium.

68. At all relevant times, Defendant had a duty to properly test, develop, design, manufacture, inspect, package, label, market, promote, sell, distribute, maintain, supply, provide proper warnings, and take such steps as necessary to ensure its Acetaminophen products did not cause users and consumers, and the user and consumer's child, to suffer from unreasonable and dangerous risks. Defendant had a continuing duty to warn Plaintiff Mother of dangers associated with Acetaminophen. Defendant, as a manufacturer, seller, and distributor of pharmaceutical medication, are held to the knowledge of an expert in the field.

69. At the time of manufacture, Defendant could have provided the warnings or instructions regarding the full and complete risks of Acetaminophen products because Defendant knew (or alternatively should have known or was willfully blind to the fact) of the unreasonable risks of harm associated with prenatal exposure and the use of and exposure to such products.

70. At all relevant times, Defendant failed and deliberately refused to investigate, study, test, or promote the safety or to minimize the dangers to users and consumers of its product and to those who would foreseeably use or be harmed by Defendant's Acetaminophen products, including Plaintiffs.

71. Defendant failed to adequately warn consumers, like Plaintiff Mother, about the significant increased risk of neurodevelopmental disorders in children exposed to APAP prenatally, including but not limited to ASD and ADHD.

72. Defendant failed to adequately inform reasonably foreseeable consumers, like Plaintiff Mother, of the proper usage of Acetaminophen products.

73. Even though Defendant knew (or alternatively should have known or was willfully blind to the fact) that Acetaminophen posed a grave risk of harm to Plaintiff Child,

Defendant failed to exercise reasonable care to warn of the dangerous risks associated with use and prenatal exposure.

74. Plaintiff Mother was exposed to Defendant's Acetaminophen products without knowledge of their dangerous characteristics.

75. At all relevant times, Plaintiff Mother used and was exposed to the use of Defendant's Acetaminophen products while using them for their intended or reasonably foreseeable purposes, without knowledge of their dangerous characteristics.

76. Plaintiff Mother could not have reasonably discovered the defects and risks associated with Acetaminophen products before consuming Acetaminophen. Plaintiff relied upon the skill, superior knowledge, and judgment of Defendant to know about and disclose serious health risks associated with using Defendant's products.

77. If Plaintiff Mother had been properly warned of the defects and dangers of the risks associated with Acetaminophen prenatal exposure, Plaintiff Mother would have utilized the products safely and with adequate protection, or have decided to not ingest the product at all.

78. Defendant is liable to Plaintiffs for injuries caused by Defendant's negligent or willful failure, as described above, to provide adequate warnings or other relevant information and data regarding the appropriate use of its Acetaminophen products and the risks associated with the use of APAP.

79. As a direct and proximate result of Defendant placing defective Acetaminophen products into the stream of commerce, and Plaintiff Mother's ingestion during pregnancy, Plaintiff Child was exposed to Acetaminophen prenatally, causing him to develop ASD and ADHD and to be diagnosed with those conditions at the age of five.

80. As a direct and proximate result of Defendant placing defective Acetaminophen products into the stream of commerce, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

Count II: Negligence

81. Plaintiffs incorporate by reference the allegations in all paragraphs above.

82. Although Defendant had a duty to use reasonable care in testing, developing, designing, manufacturing, marketing, labeling, selling, distributing, promoting, and preparing written instructions and warnings for the Acetaminophen products, Defendant failed to do so.

83. Defendant manufactured, packaged, and labeled Acetaminophen and marketed, promoted, distributed, and sold that Acetaminophen to Plaintiff Mother. At all relevant times, Defendant researched, manufactured, distributed, marketed, promoted, and sold Acetaminophen and aimed that Acetaminophen at a consumer market within this District.

84. Defendant knew (or alternatively was willfully blind to the fact), or in the exercise of reasonable care should have known, that its product was defectively and unreasonably designed, manufactured, and marketed, and was unreasonably dangerous and likely to injure persons that were prenatally exposed to it. Defendant knew (or alternatively was willfully blind to the fact or should have known) that Plaintiff Mother was unaware of the dangers and defects inherent in the Acetaminophen when she was ingesting it during her pregnancy with Plaintiff Child.

85. At all relevant times, Defendant had a duty to exercise reasonable care in the marketing, advertisement, promotion, and sale of the Acetaminophen products. Defendant's duty of care owed to consumers and the general public included providing accurate, true, and

correct information concerning the risks of using Acetaminophen during pregnancy and appropriate, complete, and accurate warnings concerning the potential adverse effects of Acetaminophen and, in particular, its significantly increased risk of causing neurodevelopmental disorders in children exposed to Acetaminophen prenatally.

86. At all relevant times, Defendant knew or, in the exercise of reasonable care, should have known of the hazards and dangers of Acetaminophen ingestion while pregnant and, specifically, the significantly increased risk of causing neurodevelopmental disorders in children exposed to Acetaminophen prenatally.

87. Defendant failed to provide any kind of warning to pregnant consumers, like Plaintiff Mother, about the significantly increased risk of causing neurodevelopmental disorders in children exposed to Acetaminophen prenatally.

88. Accordingly, at all relevant times, Defendant knew or, in the exercise of reasonable care, should have known that use of Acetaminophen products could cause Plaintiffs' injuries, and thus, create a dangerous and unreasonable risk of injury to the users of these products, including Plaintiffs.

89. As such, Defendant breached its duty of reasonable care and failed to exercise ordinary care in the design, research, development, manufacture, testing, marketing, labeling, supply, promotion, advertisement, packaging, sale, and distribution of Acetaminophen products, in that Defendant manufactured and produced defective Acetaminophen that carries the significantly increased risk of causing neurodevelopmental disorders in children exposed to APAP prenatally; knew or had reason to know of the defects inherent in its products; knew or had reason to know that a user's or consumer's use of the products created a significant risk of harm

and unreasonably dangerous side effects; and failed to prevent or adequately warn of these risks and injuries.

90. Defendant had a duty to disclose the truth about the risks associated with APAP in its promotional efforts, outside of the context of labeling. Defendant was negligent in its promotion of APAP, outside of the labeling context, by failing to disclose material risk information as part of its promotion and marketing of APAP, including the internet, television, and print advertisements.

91. Despite Defendant's ability and means to investigate, study, and test the products and to provide adequate warnings, Defendant failed to do so. Indeed, Defendant wrongfully concealed information and further made false and misleading statements concerning the safety and use of APAP.

92. Defendant's negligence included:

- a. Manufacturing, producing, promoting, formulating, creating, developing, designing, selling, and distributing Acetaminophen while negligently and/or intentionally concealing and failing to disclose the results of trials, tests, and studies of Acetaminophen and the significantly increased risk of causing neurodevelopmental disorders in children exposed to Acetaminophen prenatally, and, consequently, the risk of serious harm associated with human use of Acetaminophen during pregnancy;
- b. Failing to undertake sufficient studies and conduct necessary tests to determine whether or not Acetaminophen products were safe for its intended consumer use and unborn child;

- c. Failing to provide adequate instructions, guidelines, and safety precautions to those persons Defendant could reasonably foresee would use Acetaminophen products;
- d. Failing to disclose to Plaintiff Mother, users/consumers, and the general public that use of Acetaminophen during pregnancy presented severe risks of neurodevelopmental disorders in children exposed to Acetaminophen prenatally;
- e. Failing to warn Plaintiff, consumers, and the general public that the Acetaminophen product's risk of harm was unreasonable and that there were safer and effective alternative medications or treatments available to Plaintiff and other consumers;
- f. Representing that its Acetaminophen products were safe for its intended use for pregnant women when, in fact, Defendant knew or should have known the products were not safe for its intended purpose;
- g. Declining to make or propose any changes to Acetaminophen products' labeling or other promotional materials that would alert consumers and the general public of the risks of Acetaminophen, including pregnant women;
- h. Advertising, marketing, and recommending the use of the Acetaminophen products, while concealing and failing to disclose or warn of the dangers known by Defendant to be associated with or caused by the use of or exposure to Acetaminophen;

- i. Continuing to disseminate information to its consumers, which indicate or imply that Defendant's Acetaminophen products are not unsafe for pregnant consumer use; and
- j. Continuing the manufacture and sale of its products with the knowledge that the products were unreasonably unsafe and dangerous.

93. Defendant knew or should have known that it was foreseeable that children such as Plaintiff Child would suffer injuries as a result of Defendant's failure to exercise ordinary care in the manufacturing, marketing, labeling, distribution, and sale of Acetaminophen to consumers, like Plaintiff Mother.

94. Plaintiff Mother did not know the nature and extent of the injuries that could result in her child from the exposure to Acetaminophen prenatally.

95. Defendant's negligence was the proximate cause of Plaintiffs' injuries, i.e., absent Defendant's negligence, Plaintiff Child would not have developed ASD and ADHD.

96. Defendant's conduct, as described above, was reckless. Defendant regularly risked the development of children prenatally exposed to Acetaminophen and users of its products, including Plaintiff Mother and Plaintiff Child, with full knowledge of the dangers of its products. Defendant made conscious decisions not to redesign, re-label, warn, or inform the unsuspecting public, including Plaintiff Mother. Defendant's reckless conduct therefore warrants an award of punitive damages.

97. As a direct and proximate result of Defendant placing defective Acetaminophen products into the stream of commerce, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

Count III: Breach of express warranty

98. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

99. At all material times, Defendant manufactured, marketed, sold, distributed and otherwise placed into the stream of commerce its Acetaminophen products. These actions were under the ultimate control and supervision of Defendant.

100. In advertising, marketing, and promoting Acetaminophen to consumers, like Plaintiff Mother, Defendant expressly warranted that its product was safe for use and reasonably fit for its intended purposes. In advertising, marketing and otherwise promoting its product, Defendant intended for pregnant consumers to rely upon its representations regarding safety and fitness, in an effort to induce them to purchase and consume Acetaminophen products during pregnancy to relieve pain.

101. Defendant expressly warranted to Plaintiff Mother, and pregnant consumers, that its APAP products were safe for ingestion during pregnancy.

102. Defendant had a duty to exercise reasonable care in the research, development, design, testing, packaging, manufacture, inspection, labeling, distributing, marketing, promotion, sale, and release of Acetaminophen products, including a duty to:

- a. ensure that its Acetaminophen products did not cause the user unreasonably dangerous side effects;
- b. warn of dangerous and potentially incurable side effects; and
- c. disclose adverse material facts, such as the true risks associated with the use of and exposure to Acetaminophen during pregnancy, when making representations to consumers and the general public, including Plaintiff Mother.

103. Defendant had the ability to properly disclose the risks associated with Acetaminophen usage during pregnancy through multiple channels, not just labeling.

104. At all relevant times, Defendant expressly represented and warranted to the purchasers of its products, by and through statements made by Defendant in labels, publications, brochures, and other written materials intended for consumers and the general public, that Acetaminophen products were safe to human health and the environment, effective, fit, and proper for its intended use. Defendant advertised, labeled, marketed, and promoted Acetaminophen products to consumers and the public in such a way as to induce its purchase or use, thereby making an express warranty that Acetaminophen products would conform to the representations.

105. The representations about Acetaminophen products, as set forth herein, contained or constituted affirmations of fact or promises made by the seller to the buyer, which related to the goods and became part of the basis of the bargain, creating an express warranty that the goods would conform to the representations.

106. Defendant breached express representations and warranties made to Plaintiff Mother, with respect to its Acetaminophen products, including the following:

- a. Defendant represented through its labeling, advertising, and marketing materials that Acetaminophen products were safe, and intentionally withheld and concealed information about the risks of serious injury associated with use of Acetaminophen and by expressly limiting the risks associated with use within its warnings and labels; and
- b. Defendant represented that Acetaminophen products were safe for use and intentionally concealed information that demonstrated that

Acetaminophen carries the significantly increased risk of causing neurodevelopmental disorders in children exposed to Acetaminophen prenatally, and that Acetaminophen products, therefore, were not safer than alternatives available on the market.

107. Plaintiff Mother detrimentally relied on the express warranties and representations of Defendant concerning the safety and/or risk profile of Acetaminophen in deciding to purchase the product. Plaintiff Mother reasonably relied upon Defendant to disclose known defects, risks, dangers, and side effects of Acetaminophen. Plaintiff Mother would not have purchased or used Acetaminophen had Defendant properly disclosed the risks associated with the product, either through advertising, labeling, or any other form of disclosure.

108. Plaintiff Mother had no knowledge of the falsity or incompleteness of Defendants' statements and representations concerning Acetaminophen.

109. Plaintiff Mother used and was exposed to Acetaminophen as researched, developed, designed, tested, manufactured, inspected, labeled, distributed, packaged, marketed, promoted, sold, or otherwise released into the stream of commerce by Defendant.

110. Had the warnings, labels, advertisements, or promotional material for Acetaminophen products accurately and adequately set forth the true risks associated with the use of such products, including Plaintiffs' injuries, rather than expressly excluding such information and warranting that the products were safe for its intended use, Plaintiffs could have avoided the injuries set forth above.

111. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress,

lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

Count IV: Breach of implied warranty

112. Plaintiffs incorporate by reference the allegations in all paragraphs above.

113. At all material times, Defendant manufactured, marketed, sold, distributed and otherwise placed APAP products into the stream of commerce.

114. At all material times, Defendant intended for its product to be consumed and ingested by pregnant women, like Plaintiff Mother; and Defendant impliedly warranted that the product and its component parts were of merchantable quality, safe and fit for such use, and adequately tested.

115. Defendant was aware that consumers, including Plaintiff Mother, would consume and ingest its product as directed by products' label and promotional material. Therefore, Plaintiff was a foreseeable user of Defendant's Acetaminophen product.

116. But Defendant failed to disclose that Acetaminophen has dangerous propensities when used as intended and that use of Acetaminophen products carries an increased risk of developing severe injuries, including Plaintiff Child's injuries.

117. Defendant's Acetaminophen product was expected to reach, and did in fact reach consumers, including Plaintiff Mother, without substantial change in the condition in which it was manufactured and sold by Defendant.

118. Plaintiff Mother was an intended beneficiary of the implied warranties made by Defendant to purchasers of its Acetaminophen products.

119. In reliance upon Defendant's implied warranties, Plaintiff Mother used the Acetaminophen products as indicated, and in the foreseeable manner normally intended, recommended, promoted, and marketed by Defendant.

120. Defendant breached its implied warranties to Plaintiffs in that its product was not of merchantable quality, nor was it safe and fit for its intended use or adequately tested.

121. The harm caused by Defendant's Acetaminophen products far outweighed their benefit, rendering the products more dangerous than an ordinary consumer or user would expect.

122. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

Count V: Violation of consumer protection laws

123. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

124. Plaintiff Mother purchased and used the Acetaminophen product for personal use and pain relief during pregnancy, thereby suffering ascertainable losses as a result of Defendant's actions in violation of the consumer protection laws.

125. Had Defendant not engaged in the deceptive conduct described in this Complaint, Plaintiff would not have purchased or paid for Defendant's product, and Plaintiffs would not have incurred related injury medical costs.

126. Defendant engaged in wrongful conduct while at the same time obtaining under false pretenses moneys from Plaintiff for the Acetaminophen products. Those moneys would not have been paid had Defendant not engaged in unfair and deceptive conduct.

127. Unfair methods of competition or deceptive acts or practices proscribed by law include the following:

- a. representing that goods or services have characteristics, ingredients, uses, benefits or qualities they do not have; and
- b. advertising goods or services with the intent not to sell them as advertised; and,
- c. engaging in fraudulent or deceptive conduct creating a likelihood of confusion or misunderstanding.

128. Plaintiffs were injured by the cumulative nature of Defendants' conduct. The cumulative effect, directed at patients, physicians and consumers, was to create demand for and sell Defendant's products. Each aspect of Defendant's conduct combined to artificially create sales of the product.

129. Defendant had a statutory duty to refrain from unfair or deceptive acts or trade practices in the design, labeling, development, manufacture, promotion, and sale of its Acetaminophen products.

130. Defendant's deceptive, unconscionable, or fraudulent representations and material omissions to consumers, including Plaintiff Mother, constitute unfair and deceptive acts and trade practices in violation of the federal and state consumer protection statutes listed below.

131. Defendant's actions, as complained of in this Complaint, constitute unfair competition or unfair, unconscionable, deceptive or fraudulent acts, or trade practices in violation of the federal and state consumer protection statutes listed below.

132. Defendant has engaged in unfair competition or unfair or deceptive acts or trade practices or have made false representations under the following statutes:

- a. 15 U.S.C. §§ 2301-2312 (1982)
- b. Mo Rev. Stat. §§ 407.010, *et seq.*

133. Defendant is the supplier, manufacturer, advertiser, and seller subject to liability under the above legislation enacted against unfair, deceptive, fraudulent and unconscionable consumer sales practices.

134. By knowingly and falsely representing that its Acetaminophen products were fit to be used for the purpose for which it was intended—when in fact it was defective and dangerous—and by other acts alleged, Defendant violated the above statutes, enacted to protect consumers against unfair, deceptive, fraudulent and unconscionable trade and business practices and false advertising.

135. Defendant's actions and omissions are uncured or incurable, deceptive acts under the above legislation.

136. Defendant had actual knowledge of the defective and dangerous condition of its product but failed to take any action to cure such defective and dangerous conditions.

137. Plaintiff Mother relied upon Defendant's misrepresentations and omissions in determining which product (if any) to ingest.

138. Defendant's deceptive, unconscionable or fraudulent representations and material omissions to consumers constituted unfair and deceptive acts and practices.

139. Defendants' unlawful acts are the direct and proximate cause of Plaintiffs ascertainable harms and losses.

140. As a direct and proximate result of Defendant's violations of the above-listed legislation, Plaintiffs have sustained economic losses and other damages and are entitled to statutory and compensatory damages in an amount to be proven at trial.

Count VI: Negligent misrepresentation

141. Plaintiffs incorporate by reference the allegations in all paragraphs above.

142. Defendant had a duty to accurately and truthfully represent to consumers, including Plaintiff Mother, and the public, that the Acetaminophen product had not been adequately tested and found to be a safe and effective treatment for pregnant women. Defendant breached that duty as its representations were false.

143. Defendant failed to exercise ordinary care in the representations concerning its product while they were involved in its manufacture, sale, testing, quality assurance, quality control, and distribution in interstate commerce, because they negligently misrepresented the Acetaminophen products' high risk of unreasonable and dangerous adverse side effects.

144. Defendant also breached its duty in representing to Plaintiff Mother that its product had no serious side effects when ingested during pregnancy.

145. As a foreseeable, direct, and proximate result of Defendant's negligent misrepresentations, they knew (or alternatively was willfully blind to the fact or had reason to know) that the Acetaminophen product had been insufficiently tested, or had not been tested at all; and that it lacked adequate and accurate warnings, and created a high risk, or a higher than acceptable reported and represented risk of adverse side effects. Those side effects include neurodevelopmental disorders in children, such as ASD and ADHD.

146. As a direct and proximate result of Defendant's breach of express warranty, Plaintiffs have suffered permanent injuries and significant pain and suffering, emotional distress, lost wages and earning capacity, and diminished quality of life. Plaintiffs respectfully seek all damages to which they may be legally entitled.

Punitive damages

147. Plaintiffs incorporate by reference the allegations in all prior paragraphs.

148. Defendant failed to adequately test and study the Acetaminophen product to determine and ensure that the product was safe and effective prior to releasing it for sale for human consumption.

149. Further, Defendant continued to manufacture and sell the product after obtaining knowledge and information that it was defective and unreasonably unsafe in that it did not include an adequate warning.

150. Defendant was aware of the probable consequences of the dangerous and defective product, including the risk of neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered prenatal exposure.

151. At all material times, Defendant knew (or alternatively was willfully blind to the fact or should have known) that APAP products were inherently dangerous with respect to the following: the risk of neurodevelopmental disorders in children, such as ASD and ADHD, when they suffered prenatal exposure, pain and suffering, loss of life's enjoyment, and unsuccessful treatments to cure the conditions proximately caused by use of the product, as well as the other permanent and severe personal injuries.

152. Defendant's misrepresentations included knowingly withholding material information from consumers and the public, including Plaintiff Mother, concerning the safety and efficacy of the Acetaminophen products, which deprived Plaintiff Mother of vitally necessary information with which to make a fully informed decision about whether to use the product.

153. At all material times, Defendant also knew and recklessly and/or intentionally disregarded the fact that its product can cause debilitating and life-altering side effects with greater

frequency than safer alternative methods, products, and/or treatments. But Defendant recklessly failed to advise the medical community and the general public, including Plaintiff Mother, of that fact.

154. At all material times, Defendant intentionally misstated and misrepresented data; and they continue to misrepresent data so as to minimize the perceived risk of injuries and the rate of complications caused by or associated with the Acetaminophen product.

155. Notwithstanding the foregoing and the growing body of knowledge and information regarding the true and defective nature of the Acetaminophen product, with its increased risk of side effects and serious complications, Defendant continues to aggressively market the product to consumers, including the pregnant community at large, without disclosing the true risk of the complications and side effects.

156. When Plaintiff Mother consumed the Acetaminophen products and since then, Defendant has known the product was defective and unreasonably dangerous without an adequate warning. But they continued to manufacture, produce, assemble, market, distribute, and sell Acetaminophen products to the pregnant community so as to maximize sales and profits at the expense of the health and safety of expecting mothers in a conscious, reckless and/or intentional disregard of the likely and foreseeable harm caused by the product to members of the public, including Plaintiff Mother.

157. At all material times, Defendant has concealed and failed to disclose to the public the serious risks and the potential complications associated with the product, so as to ensure continued and increased sales and profits and to the detriment of the public, including Plaintiffs.

158. Defendant's acts and omissions are of such character and nature so as to entitle Plaintiffs to an award of punitive damages in accordance with applicable statutory and common

law. Defendant's conduct shows willful misconduct, malice, fraud, wantonness, oppression, or that entire want of care, raising the presumption of conscious indifference to consequences, thereby justifying an award of punitive damages.

WHEREFORE, Plaintiffs demand judgment against Defendant individually and jointly and severally. Plaintiffs also request compensatory damages, punitive damages or enhanced compensatory damages, together with interest, costs of suit, attorneys' fees, and such further relief as the Court deems equitable and just.

Prayer for relief

Plaintiffs demand judgment against Defendant, individually and jointly and severally, and prays for the following relief in accordance with applicable law and equity:

- i. Compensatory damages to Plaintiffs for past, present, and future damages, including pain and suffering for severe and permanent personal injuries sustained by Plaintiffs; permanent impairment, mental pain and suffering, loss of enjoyment of life, health and medical care costs, economic damages, together with interest and costs as provided by law;
- ii. Restitution and disgorgement of Defendant's profits;
- iii. Punitive or enhanced compensatory damages;
- iv. Reasonable attorneys' fees as provided by law;
- v. Past and future costs of all proceedings;
- vi. All ascertainable economic damages;
- vii. Prejudgment interest on all damages as allowed by law; and
- viii. Such other and further relief as this Court deems just and proper.

Demand for jury trial

Plaintiffs hereby demand a trial by jury on all issues so triable.

/s/ John J. Gates

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